

United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Interstate Movement
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Frisby Smith	PERMIT NUMBER:	P526P-17-02245
ORGANIZATION:	Bayer US - Biologics	APPLICATION NUMBER:	P526-171121-013
ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	FACILITY NUMBER:	3279
MAILING ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	HAND CARRY:	No
PHONE:	916-661-3322	DATE ISSUED:	03/28/2018
FAX:		EXPIRES:	03/28/2021
DESTINATION:	Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605		
RELEASE:	No		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Belonolaimus longicaudatus	Adult, Egg, Juveniles, Pest-infected plant material	Research - Lab	AL, FL, GA, NC, Continental U.S.	Originally Collected from Within the Continental U.S.	BI-NC, BI-AL, BI-FL, BI-GA
Heterodera glycines	Adult, Egg, Juveniles, Pest-infected plant material	Research - Growth Chamber (lab included)	NC, Continental U.S., AL, Continental U.S.	Originally Collected from Within the Continental U.S.	H-gly-NC, H-gly-AL
Meloidogyne incognita	Adult, Egg, Juveniles, Pest-infected plant material	Research - Greenhouse (growth chamber and lab included)	AL, FL, GA, Continental U.S.	Originally Collected from Within the Continental U.S.	M-inc-NC, M-inc-AL, M-inc-FL, M-inc-GA
Meloidogyne javanica	Adult, Egg, Juveniles, Pest-infected plant material	Research - Greenhouse (growth chamber and lab included)	AL, FL, GA, Continental U.S.	Originally Collected from Within the Continental U.S.	M-jav-NC, M-jav-AL, M-jav-FL, M-jav-GA
Pratylenchus neglectus	Adult, Egg, Juveniles, Pest-infected plant material	Research - Greenhouse (growth chamber and lab included)	NC, Continental U.S., AL, Continental U.S.	Originally Collected from Within the Continental U.S.	P-neg-NC, P-neg-AL

PERMIT GUIDANCE

Permit Number P526P-17-02245

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.



Carl Schulze

DATE

03/28/2018

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury (see <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx> for current country/regional listings) for current country listings.

This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology). If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.shtml.

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your States Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

You must abide by all local quarantines see: http://www.aphis.usda.gov/planthealth/pests_and_diseases

Of special concern for movement of soil from certain continental areas are:


FRUIT FLIES: 7 CFR 301.32
WITCHWEED: 7 CFR 301.80
IMPORTED FIRE ANTS: 7 CFR 301.81
GOLDEN NEMATODES: 7 CFR 301.85
POTATO/PALE CYST NEMATODE: 7 CFR 301.86
PHYTOPHTHORA RAMORUM (Sudden Oak Death): 7 CFR 301.92
CFR (Code of Federal Regulations): <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>

PERMIT CONDITIONS

This permit authorizes the interstate movement of pure cultures of the listed organisms or host material infected with the listed organisms from various researchers within the continental United States to Frisby Smith at Bayer US - Biologics in West Sacramento, California for laboratory, growth chamber and restricted greenhouse research in Containment Facility #3279 (CF#3279).

Research with *Belonolaimus longicaudatus* is restricted to laboratory use only. Plant inoculations using *Heterodera glycines* are restricted to the laboratory and growth chambers. Plant inoculations using the other organisms listed on the permit are authorized in the laboratory, growth chambers, and greenhouse.

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1. The permit holder must:
 - (a) comply with all requirements and permit conditions,
 - (b) maintain a valid permit so long as the regulated organisms are alive,
 - (c) this permit cannot be assigned or transferred to other persons.
 - (d) permittee must maintain a residence in the United States
 - (e) safeguard and dispose of the regulated organisms during the term of this permit,
 - (f) take all necessary precautions to prevent the unauthorized release of regulated organisms. In the event of an unauthorized release, the permit holder must notify the permit unit,
 - (g) adequately mitigate environmental impacts resulting from unauthorized release of regulated organisms,
 - (h) contain any/all organisms not authorized under this permit,
 - (i) notify the permit unit of the receipt of unauthorized organisms,
 - (j) notify the permit unit if facilities are destroyed or decommissioned for any reason,
 - (k) maintain an official permanent work assignment at the address on this permit,
 - (l) notify the permit unit in advance of any change in the permit holder's work assignment,
 - (m) destroy all regulated organisms prior to departure unless other arrangements are confirmed by the permit unit prior to the permit holder's departure, and
 - (n) notify the permit unit of the destruction of regulated organisms.

Notifications to the permit unit must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

2. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agricultural Select Agent Program (ASAP) immediately by phone at 301-851-3300, and within seven (7) days submit APHIS/CDC Form 4 (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, ASAP; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa_import_into_us/sa_ag_select_agent/ct_ag_bioterr_toxinlist/). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002.
3. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated organisms authorized under this permit.
4. All persons working with these organisms must be informed of these permit conditions. Anyone working with these organisms must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

Note: these conditions may be copied and stored electronically for electronic signature and

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initialing provided that the permit number, authorized organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

5. All organisms and/or infected plant material must be shipped in packages of such materials and/or construction so as to prevent the unauthorized dissemination or release of regulated articles.
6. The permit holder is responsible for correctly identifying counties under soil quarantines (see Permit Guidance section) and ensuring samples from those counties are shipped in accordance with quarantine requirements.
7. Upon receipt, all packages must be opened within a laminar flow biosafety cabinet, that meets or exceeds Class II, Type A, in or associated with the permit holder's assigned laboratory facilities within CF#3279 to ensure the shipment contains only permitted organisms and is free of contaminants. Cultures must be in sealed containers during transport to or within the permit holder's assigned laboratory facilities.
8. All packing materials in contact with plant pests or contaminants and all leftover organisms, plant material, soil, etc., must be sufficiently heat or chemically treated to kill, denature, or destroy all plant pests prior to disposal.
9. All waste water, soil and debris from laboratory procedures must be collected and sufficiently treated by heat or chemical means to kill or destroy all nematode life stages prior to disposal.
10. Nematodes and inoculated plants must be handled appropriately (e.g. wear adequate protective clothing, practice adequate hand and shoe sanitation, disinfect all work surfaces after use) so that movement of plant pests out of the facility does not occur. Used disposable items must be collected when leaving the work area. Used disposable items must be sufficiently treated to kill all nematode life stages prior to disposal.
11. Plant inoculations and subsequent disease development must occur in laboratories, growth chambers and/or greenhouses within CF#3279 that have been inspected and found adequate for containment of the organisms received under this permit. Access to laboratories, growth chambers and/or greenhouses must be restricted to authorized personnel.
12. Research with *Belonolaimus longicaudatus* is restricted to laboratory use only. Plant inoculations using *Heterodera glycines* are restricted to the laboratory and growth chambers.

Plant inoculations using the other organisms listed on the permit are authorized in the laboratory, growth chambers, and greenhouse.

13. Runoff water from inoculated plants must be collected and sufficiently treated by heat or chemical means, or be handled in such a way as to prevent movement of all nematode life stages into adjacent agricultural or environmental areas.
14. Organisms must be maintained or stored in the permit holder's research facilities within CF#3279. All stored organisms must be kept in a locked area with access restricted to authorized personnel.


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15. A separate authorization from USDA APHIS (a new PPQ 526 permit) is required for the possession/ maintenance of live regulated organisms received under this permit beyond the expiration of this permit. Otherwise, all regulated organisms received under this permit must be devitalized prior to the expiration of this permit.
16. At the conclusion of all experiments infested soil, infested growing media and infected/infested plant materials must be treated by heat or chemical means sufficient to kill or destroy all plant pest life stages prior to disposal. All laboratory equipment and supplies must be decontaminated prior to reuse or disposal.
17. If using an autoclave the following protocol must be used:
 - a. Waste must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes.
 - b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
 - c. The autoclave must be professionally calibrated annually and a written record must be maintained.
 - d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 degrees C. You must follow the manufacturers instructions. If any growth is observed, you must have the autoclave serviced and retested.
18. There is to be no further movement or distribution of organisms without prior approval from State and Federal regulatory officials.
19. Under the Plant Protection Act, individuals or corporations who fail to comply with these conditions and authorizations, or who forge, counterfeit, or deface permits or shipping labels may receive civil or criminal penalties, and may have all current permits cancelled and future permit applications denied.

END OF PERMIT CONDITIONS

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